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PUBLIC MEETING NOTICE: CONTROLLED SUBSTANCE COMMITTEE "Special Meeting"

DATE AND TIME: **Tuesday, June 17, 2014 at 5:30 p.m.**
PLACE: **Governor Bacon Health Center, New Castle, DE**
APPROVED: **August 27, 2014**

MEMBERS PRESENT

Michael Kremer, DMD, Dental Representative, President
Stephen Ruggles, PA-C, PA Representative
Luis Garcia, Jr., DPM, Podiatric Representative, Vice President
Jo Ann M. Baker, MSN, RN, FNP-C, Nursing Representative
Herb E. Von Goerres, R.Ph., Pharmacy Representative
Alex Zarrow, R.Ph., Pharmacy Representative
Mark Hanna, Public Representative
David W. Dryden, R.Ph., J.D., Director Office of Controlled Substances
Philip Kim, M.D., Medical Representative (arrived late after vote)

MEMBERS ABSENT

Art Jankowski, VMD, Veterinary Representative

DIVISION STAFF/DEPUTY ATTORNEY GENERAL

David Mangler, Director
Christine Mast, Administrative Specialist III
Eileen Kelly, Deputy Attorney General
Samantha Nettesheim, PMP Administrator

ALSO PRESENT

Hooshang Shanehsaz, DPS

CALL TO ORDER

Dr. Kremer called the meeting to order at 5:31 pm.

NEW BUSINESS

Ms. Eileen Kelly took the floor to start the hearing. She introduced herself, and she requested that the committee members introduce themselves. After the introductions Ms. Kelly proceeded with the hearing. Pursuant to 16 Del.C. § 4731, the Delaware Controlled Substance Advisory Committee has proposed revisions to its rules and regulations. On June 18, 2014, the Secretary of State issued a Final

Order adopting emergency regulations, in the form of a new Rule 11.0, placing requirements on the prescription of extended release hydrocodone lacking an abuse-deterrent formulation. Pursuant to the Administrative Procedure Act, this rule will only be effective for a maximum of 120 days, but may be renewed once for an additional period of sixty days. Ms. Kelly presented the following exhibits to the committee: Exhibit #1, Article from nymagazine.com, "Controversial FDA Approval of Zohydro and America's Infatuation with Opioids". Exhibit #2, Article from CNN "New Pain Pill's Approval: Genuinely Frightening". Exhibit #3, Excerpt from Drugs.com, concerning extended release hydrocodone, Exhibit #4, article from fiercepharma.com, "Groups Urge Vermont Governor to Broaden Zohydro Rules". Exhibit #5, Draft Regulations setting forth requirements for the prescription of: extended-release hydrocodone. Ms. Kelly read the emergency regulation to the committee. The committee discussed the exhibits presented and the effects of the drug on the public. A motion was made by Dr. Kremer seconded by, Ms. Baker to approve the emergency rule as presented. The motion carried unanimously.

NEXT SCHEDULED MEETING

The next regular meeting will be held on Wednesday, August 27, 2014, at 9:00 am at the Buena Vista Conference Center.

ADJOURNMENT

A motion was made by Mr. Von Goerres, seconded by Mr. Ruggles, to adjourn the meeting. The motion unanimously carried. The meeting adjourned at 6:47 pm.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Christine Mast". The signature is fluid and cursive, with the first name "Christine" written in a larger, more prominent script than the last name "Mast".

Christine Mast
Administrative Specialist III
Office of Controlled Substances